

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Corrigan:

I, Dan Lieberman, M.D., declare as follows:

1. I am the Applicant for the patent application entitled "METHOD AND APPARATUS FOR IRRIGATION AND DRAINAGE OF THE BRAIN'S SUBDURAL SPACE USING A PERCUTANEOUS APPROACH," Ser. No. 10/646,903, filed August 22, 2003 and the inventor of the subject matter described and claimed therein.

2. I am a board certified neurosurgeon. I have been in practice since 2000. My practice includes the management of hundreds of ~~patients with subdural hematomas, which are a routine occurrence~~ in neurosurgical practice.

3. After a careful review of the prior art cited by the examiner, and based upon all of my years of experience in the field of neurosurgery generally and subdural hematomas specifically, the medical devices cited by the examiner in the Wild patent and Dardik et al Journal of Vascular Surgery article are not used for the treatment of subdural hematomas. There are several important differences between the techniques for suctioning a hematoma and flushing the evacuated space with fluid as compared to the techniques for endoscopy. An endoscope is a rigid device which limits entry under the bone flap to between approximately 1-2 millimeters. Conversely, a catheter that is not encumbered by a camera, such as the dual-lumen catheter that is the subject of my patent application, is capable of being inserted approximately 5-10 centimeters under the bone flap. This enormous difference is why endoscopy is not practical when treating subdural hematomas. Furthermore, endoscopic surgery can only be used in conjunction with fluid, and cannot be used in anatomical structures in which little or no fluid is present. The use of fluid described in the Wild patent is not for purposes of irrigating and draining a subdural space, but rather to continuously clear debris from the optical lens of the telescope. In treating subdural hematomas the first step must be to drain the subdural space. The Wild device cannot be used for this purpose since its use of a drainage

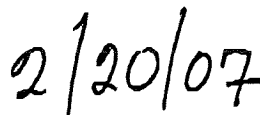
channel is only for purposes of removing the very fluid that is being irrigated to clear the optical lens. There is no discussion of using the Wild device for the treatment of subdural hematomas (the only reference to the treatment of subdural hematomas included in the Wild reference relates to a discussion of prior art neurosurgery devices that stand in contrast to the endoscopic Wild device).

4. I further declare that all statements made herein are of my own knowledge and all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the above-referenced application and any patent issuing therefrom.

FURTHER DECLARANT SAYETH NOT.



Dan Lieberman, M.D.



Date